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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,559	05/14/2002	Masayuki Yanagi	2026-4302US	8862

7590

02/24/2004

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EXAMINER
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LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/980,559

**Applicant(s)**

YANAGI ET AL.

**Examiner**

Bao Qun Li

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 12-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/05/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-37 are pending.

#### *Election/Restrictions*

1. Applicant's election without traverse of Group I, claims 1-5, 8-9 and 37 in Paper No. 7 is acknowledged.
2. Upon considering the claims 6-7 and 10-11, they are rejoined with claims 1-5, 8-9 and 37 are considered before the examiner.
3. Claims 12-36 are withdrawn from the consideration.

#### *Claim Rejections - 35 USC § 102/103*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4-11 and 37 are rejected under 35 U.S.C. 102(a) as anticipated by Rice et al (US Patent No. 5, 874,565A) in light of teach of Doorn et al. (J. Gen. Virol. 1995, Vol. 76, pp. 1871-1876) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rice et al (US Patent No. 5, 874,565A) and further in view of Yoo et al. (J. Virol. 1995, Vol. 69, No. 1, pp. 32-38).
7. Claimed invention is directed to a purified and isolated nucleic acid molecule that encodes genotype 2a HCV, wherein the said nucleic acid molecule is capable of expressing said virus when transfected into cells. The nucleic acid molecule is directed to a DNA or a RNA transcript of the DNA molecule and a cell line comprising the said DNA or RNA molecule.

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7. Rice et al. disclose an isolated polynucleotide encoding a HCV genotype of HC-J6 isolate, which belongs to HCV genotype 2a in light of disclosure of Doorn et al. (J. Gen. Virol. 1995, Vol. 76, pp. 1871-1876, see Fig. 1 on page 1873). The invention of Rice et al. is also directed to a cell line comprising the DNA or RNA molecule of the claimed polynucleotide. Regarding to the functional limitation of the claimed molecule is capable of expressing said virus when transfected into cells, because both claimed invention and prior art are directed to a HCV genotype 2a nucleic acid sequence, as the independent claim 1 does not recite what the precise structure of the isolated HCV genotype 2a is, the examiner considers that both nucleic acid molecule encoding the same genotype of HCV 2a would inherently possess same biological function as claims drafted now. Therefore, the claims are anticipated by the cited reference.

8. Or alternatively, it would have been obvious for a person with ordinary skill in the art to be motivated by the disclosed prior art to express the HCV virus in view of the disclosure Yoo et al. because Yoo explicitly teach a method for using the Huh7 cells to produce infectious HCV by transfecting the cells with a composition comprising the HCV RNA transcript from the HCV DNA molecule (See entire document, especially the first col. of page 33). Hence the claimed invention as a whole is prima facie obvious absent unexpected results.

***Claim Rejections - 35 USC § 102/103***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1 and 4-11 are rejected under 35 U.S.C. 102(b) as anticipated by Okamoto et al. (J. Gen. Virol. 1991, Vol. 72, pp. 2697-2704) in light of disclosure of Doorn et al. (J. Gen. Virol. 1995, Vol. 76, pp. 1871-1876, see Fig. 1 on page 1873) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Okamoto et al. (J. Gen. Virol. 1991, Vol. 72, pp. 2697-2704) and further in view of Yoo et al. (J. Virol. 1995, Vol. 69, No. 1, pp. 32-38).

12. Claimed invention is directed to a purified and isolated nucleic acid molecule that encodes genotype 2a HCV, wherein the said nucleic acid molecule is capable of expressing said virus when transfected into cells. The nucleic acid molecule is directed to the DNA or RNA transcript of the DNA molecule and a cell line comprising the said DNA or RNA molecule.

13. Okamoto et al. disclose a purified and isolated DNA and RNA molecules of human hepatitis C virus genotype HC-J6 isolate, which belongs to the HCV genotype 2a in light of disclosure of Doorn et al. (J. Gen. Virol. 1995, Vol. 76, pp. 1871-1876, see Fig. 1 on page 1873). Regarding to the functional limitation of the claimed molecule is capable of expressing said virus when transfected into cells, because both claimed invention and prior art are directed to a HCV genotype 2a nucleic acid sequence, as the independent claim 1 does not recite what the precise structure of the isolated HCV genotype 2a is, the examiner considers that both nucleic acid molecule encoding the same genotype of HCV 2a would inherently possess same biological function as claims drafted now.

14. Or alternatively, it would have been obvious for a person with ordinary skill in the art to be motivated by the disclosed prior art to express the HCV virus in view of the disclosure Yoo et al. because they explicitly teach a method for using the Huh7 cells to establish the long-term culture persistently express HCV by transfecting the cells with the HCV RNA transcript from the HCV DNA molecule (See entire document, especially the first col. of page 33). Hence the claimed invention as a whole is prima facie obvious absent unexpected results.

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***Conclusion***

Claims 2-3 are deemed free of art. However, they are not in the condition for allowance because they dependent on the rejected claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number: 571-272-0904. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

February 19, 2004

Handwritten signature of James C. Housel in black ink, with the date 2/23/04 written below it.

JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600